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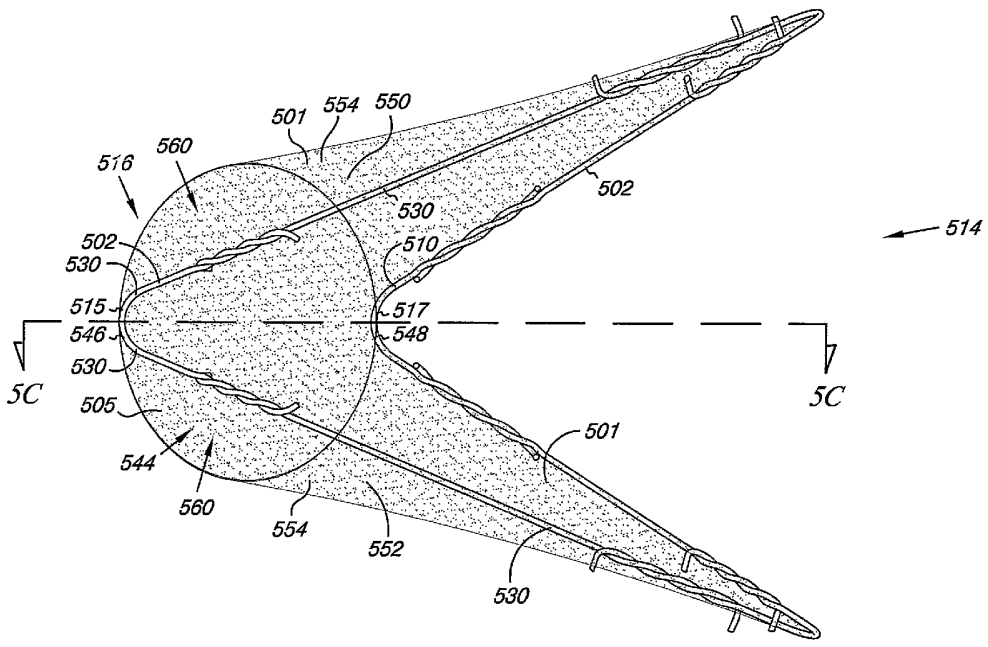
(54) **Title:** VENOUS VALVE APPARATUS, SYSTEM, AND METHOD



(57) **Abstract:** A venous valve (514) with a frame (502) and a cover (501) on the frame for unidirectional flow of a liquid through the valve . The frame includes one or more elongate members that form a closed circumference by entwining portions near the end portions of the elongate members . The end portions may extend radially to form barbs.

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

Venous Valve Apparatus, System, and Method

Field of the Invention

The present invention relates generally to apparatus, systems, and methods for use in a lumen; and more particularly to venous valve apparatus, systems, and methods for use in the vasculature system.

Background of the Invention

The venous system of the legs uses valves and muscles as part of the body's pumping mechanism to return blood to the heart. Venous valves create one way flow to prevent blood from flowing away from the heart. When valves fail, blood can pool in the lower legs resulting in swelling and ulcers of the leg. The absence of functioning venous valves can lead to chronic venous insufficiency.

Techniques for both repairing and replacing the valves exist, but are tedious and require invasive surgical procedures. Direct and indirect valvuoplasty procedures are used to repair damaged valves. Transposition and transplantation are used to replace an incompetent valve. Transposition involves moving a vein with an incompetent valve to a site with a competent valve. Transplantation replaces an incompetent valve with a harvested valve from another venous site. Prosthetic valves can be transplanted into the venous system, but current devices are not successful enough to see widespread usage.

Brief Description of the Drawings

Figs. 1A-1B illustrate an embodiment of a valve.

Fig. 2A illustrates an embodiment of a valve.

Fig. 2B illustrates an embodiment of a valve in a segment view.

Fig. 3 illustrates an embodiment of a valve.

Figs. 4A-4G illustrate embodiments of cross-sectional geometries for use with embodiments of a valve.

Figs. 5A-5D illustrate an embodiment of a valve.

Figs. 6A-6B illustrate a valve in an expanded and a collapsed state.

Fig. 7 illustrates an embodiment of a system that includes a valve.

Fig. 8 illustrates an embodiment of a system that includes a valve.

Fig. 9 illustrates an embodiment of a system that includes a valve.

Detailed Description

Embodiments of the present invention are directed to an apparatus, system, and method for valve replacement or augmentation. For example, the apparatus can include a valve that can be used to replace or augment an incompetent valve in a body lumen. Embodiments of the valve can include a frame and cover that can be implanted through minimally-invasive techniques into the body lumen. In one example, embodiments of the apparatus, system, and method for valve replacement or augmentation may help to maintain antegrade blood flow, while decreasing retrograde blood flow in a venous system of individuals having venous insufficiency, such as venous insufficiency in the legs.

The figures herein follow a numbering convention in which the first digit or digits correspond to the drawing figure number and the remaining digits identify an element or component in the drawing. Similar elements or components between different figures may be identified by the use of similar digits. For example, 110 may reference element "10" in Fig. 1, and a similar element may be referenced as 210 in Fig. 2. As will be appreciated, elements shown in the various embodiments herein can be added, exchanged, and/or eliminated so as to provide a number of additional embodiments of the valve according to the present invention. In addition, discussion of features and/or attributes for an element with respect to one Fig. can also apply to the element shown in one or more additional Figs.

Figs. 1A-1B, 2A-2B, and 3 provide illustrations of various embodiments of a valve of the present invention. Generally, the valve can be implanted within the fluid passageway of a body lumen, such as for replacement or augmentation of a valve structure within the body lumen (e.g., a venous valve). In one embodiment, the valve of the present invention may be beneficial to regulate the flow of a bodily fluid through the body lumen in a single direction.

Fig. 1A illustrates one embodiment of a venous valve 100. Venous valve 100 includes a frame 102 and a cover 101, where both the frame 102 and the

cover 101 can resiliently collapse and expand, as will be discussed herein. The frame 102 and the cover 101 can define a lumen 105 of the valve 100. Lumen 105 allows for, among other things, fluid to move through the valve 100. The frame 102 can be expanded to provide the lumen (e.g., 105 in Figs. 1A-1B, 205 in Fig. 2A, and 305 in Fig. 3) having a number of sizes. For example, the size of the lumen can be determined based upon the type of body lumen and the body lumen size in which the valve is to be placed.

The frame 102 can include one or more elongate members 104. The elongate member 104 can include a first member end 106 and a second member end 108. The frame 102 illustrated in Fig. 1A includes a single elongate member 104. However, in various embodiments, the frame 102 can have a plurality of elongate members. For example, in Fig. 2A, the frame includes four (4) elongate members 204-1 through 204-4, and in Fig. 3, the frame includes eight (8) elongate members 304-1 through 304-8.

The first and second member ends 106 and 108 of the elongate member 104 can extend radially from an outer surface 110 of the frame 102 relative a central longitudinal axis 112. In one embodiment, the radial extensions of the first and second member ends 106 and 108 can function to engage and attach to a body lumen, e.g., a vein, for securing the frame 102 within a body lumen as will be discussed herein. In addition, the first and second member ends 106 and 108 can extend parallel to the elongate member 104. In such embodiments, the first and second member ends 106 and 108 can be positioned adjacent to and parallel to the elongate member 104 of the frame 102 such that the first and second member ends 106 and 108 point toward the vertices of the frame.

In the various embodiments of the present invention, the first and second member ends 106 and 108 can extend radially from the outer surface as illustrated in Fig. 1A, and/or they can extend adjacent to and parallel to the elongate member 104 of the frame 102. In some embodiments, the first and second member ends 106 and 108 can include anchoring elements, e.g., barbs, for engaging and attaching to a body lumen as will be discussed herein.

The elongate member 104 further includes a predetermined portion 107-1 and 107-2 adjacent the first and second member ends 106 and 108. As used herein, the predetermined portion 107-1 and 107-2 includes a section of the elongate member 104 adjacent the first member end 106 and the second member

end 108 that can be used to engage each other thereby forming a closed circumference of the frame 102. For example, as illustrated in Fig. 1A, the predetermined portion 107-1 adjacent the first member end 106 and the predetermined portion107-2 adjacent the second member end 108 entwine to form a closed circumference of the frame 102.

The entwined predetermined portions 107-1 and 107-2 can include a number of twists having a range of twists from 1 twist(s) to 4 twists. As used herein, a twist can include a predetermined portion rotated once around another predetermined portion. For example, in the embodiment shown in Fig. 1A, the predetermined portion 107-1 includes two rotations around predetermined portion 107-2 and predetermined portion 107-2 includes two rotations around predetermined portion 107-1. Thus, in this embodiment, the predetermined portions 107-1 and 107-2 entwine to include two twists each to form the closed circumference of the frame 102. As will be appreciated, fractional values for a twist are possible (e.g., 1.5 twists) along with twist values less than 1 twists and greater than 4 twists.

The frame 102 can further be configured to include vertices relative a first end 114 and a second end 116 of the frame 102. The frame 102 can include a series of bends to provide the vertices relative the first and the second ends 114 and 116 of the frame 102. For example, the frame 102 can include four corner portions 119 having bends that include a first vertex 111, a second vertex 113, a third vertex 115, and a fourth vertex 117. The corner portions 119 of the frame 102 provide the first vertex 111 and the second vertex 113 relative the second end 116 of the frame 102. The corner portions 119 also provide the third vertex 115 and the fourth vertex 117 at the second end 116 relative the first and second vertices 111 and 113. In one embodiment, the first vertex 111 and the second vertex 113 are positioned opposite each other along a first common axis 138 at the first end 114 of the frame 102. Similarly, the third vertex 115 and the fourth vertex 117 are positioned opposite each other along a second common axis 140. Other relative positions for the vertices 111, 113, 115, and 117 are also possible.

In the various embodiments described herein, the corner portions 119 of the frame 102 can provide a spring force against radial compression of the frame 102. The corner portions 119 can further provide elastic regions for the frame

102. Typically, these elastic regions occur at bent portions, i.e., corner portions 119, of the frame 102 forming the vertices. In one embodiment, the elastic regions allow the valve 100 to accommodate changes in body lumen size (e.g., diameter of the body lumen) by flexing to expand and/or contracting to change the radial shape of the frame 102. In one embodiment, the corner portions 119 of the frame 102 can act as springs to allow the valve 100 to resiliently radially collapse and expand. The frame 102 can also provide sufficient contact and expansion force with the surface of a body lumen wall to encourage fixation of the valve 100 and to prevent retrograde flow within the body lumen around the edges of the frame 102 and the surface of a lumen when combined with a closed state of the valve leaflets (described in more detail below) attached thereto.

The frame 102 can further include elongate portions 120, 122, 124, and 126. As used herein, an elongate portion includes a portion of the frame 102 that extends between the vertices of the frame 102. For example, as illustrated in Fig. 1A, a first elongate portion 120 can extend from approximately the first vertex 111 to approximately the second vertex 115. Similarly, a second elongate portion 122 can extend from approximately the first vertex 111 to approximately the fourth vertex 117. Thus, in various embodiments, an elongate portion can include at least one elongate member 104, and possibly predetermined portion 107-1 and 107-2 including the first and a second member ends 106 and 108.

As illustrated in Figs. 1A and 1B, the frame 102 can have similar and/or different cross-sectional geometries along its length. The similarity and/or the differences in the cross-sectional geometries can be based on one or more desired functions to be elicited from each portion of the frame 102 (e.g., the elongate portion 120, 122, 124, 126, and the vertices 111, 113, 115 and 117). For example, Fig. 1A provides an illustration of the similar cross-sectional geometry, where the frame 102 includes a circular cross-section along the length of the frame including the predetermined portion 107-1 and 107-2, and the first and second member ends 106 and 108 respectively.

Alternatively, Fig. 1B provides an illustration of the varying cross-sectional geometry. In Fig 1B, the frame 102 can include a strip 118 having a rectangular cross-section along the elongate portions 120, 122, 124, and 126 of the frame 102. In this embodiment, the elongate portions 120, 122, 124, and 126 each include a planar inner surface 130 and a planar outer surface 110 with the

other portions of the frame 102 surfaces having a non-planar configuration. That is, the predetermined portion 107-1 and 107-2, and the corner portions 119 including the vertices 111, 113, 115, and 117 of the frame 102, can have one or more of a round (e.g., circular, oval, and/or elliptical) cross-sectional geometry, while the elongate portions 120, 122, 124, and 126 can have a rectangular cross-sectional geometry.

As shown in Fig. 1B, the corner portions 119 of the vertices 111, 113, 115, and 117 have a circular cross-sectional geometry. As will be appreciated however, each of the corner portions 119 of the frame 102 can themselves have similar and/or different cross-sectional geometries (e.g., corner portions 119 of vertices 111 and 113 could have a circular cross-sectional geometry, while the corner portions 119 of vertices 115 and 117 could have an elliptical cross-sectional geometry). Other combinations of cross-sectional geometries are possible.

In the embodiment of Fig. 1B, the strip 118 of material forming the elongate portions 120, 122, 124, and 126 of the frame 102 can include a dimension of height 132 and width 134 between the inner surface 130 and the outer surface 110 so as to provide an aspect ratio of the width 134 to the height 132. As will be appreciated, the aspect ratio can have one or more values that provide the frame 102 with sufficient strength, flexibility and/or rigidity for the environment, including the physical demands, in which the venous valve 100 is to be used. Embodiments of the invention are not so limited.

In addition, the cross-sectional geometries can include varying dimensions along the length of the valve 100. For example, in the embodiment shown in Fig. 2B, illustrated as a section of the frame 202, the cross-sectional diameter 247 of the predetermined portion 207-1 and 207-2 is the same as the cross-sectional diameter 246 of the elongate members 204-1 and 204-2. In this embodiment, each predetermined portion 207-1 and 207-2 has a cross-sectional diameter half the size of the cross-sectional diameter of the elongate members 204-1 and 204-2. As a result of the predetermined portion 207-1 and 207-2 being entwined, the closed circumference of the frame 202 has a single uniform diameter along its length. That is, the diameters 246 of the elongate members 204-1 and 204-2 equal the diameter 247 of the entwined predetermined portion 207-1 and 207-2.

While the elongate portions 120, 122, 124, and 126 are illustrated herein as having a circular and planar cross-sectional configuration as shown in Figs. 1A and 1B, other configurations are also possible. For example, Figs. 4A-4G provide non-limiting examples of cross-sectional geometries for the elongate member 104 (e.g., elongate portions 120, 122, 124, and 126) of the frame 102. As shown in Figs. 4A-4G, examples of cross-sectional geometries include, but are not limited to, rectangular geometries having perpendicular sides (Fig. 4A), one or more convex sides (Fig. 4D), and one or more concave sides (Fig. 4E), semi-circular (Figs. 4B and 4F), circular (Fig. 4G) and triangular (Fig. 4C).

As will be appreciated, the dimensions of the cross-sectional geometries of the different parts of the frame 102, e.g., the first and second member ends 106 and 108, the predetermined portion 107-1 and 107-2, and the one or more elongate members 104 can each be determined based upon the location into which the valve 100 is to be implanted in the patient. Thus, in the various embodiments of the present invention, the various parts of the frame can each include a cross-sectional geometry having various widths 134, and heights 132. For example, the elongate portions 120, 122, 124, and 126, as seen in Fig. 1B, can each include the cross-sectional geometry shown in Fig. 4A and the corner portions 119 can each include the circular geometry, such as the cross-sectional geometry shown in Fig. 4G. Other combinations of cross-sectional geometries are also possible.

Additional examples of cross-sectional geometries for one or more portions of the frame 102 include, but are not limited to, tubular, I-shaped, T-shaped, oval, and trapezoidal. These embodiments, however, are not limited to the present examples as other cross-sectional geometries are also possible. As such, the present invention should not be limited to the illustration of the frame in Figs. 1A-1B, 2A-2B and 3.

In addition to cross-sectional geometries for the one or more portions of the frame 102, the frame can exhibit partial helical twisting. For example, the frame 102 in Fig. 1B can further include at least a partial helical configuration 136 in the elongate portions 120, 122, 124, and 126. The elongate portion 120 of frame 102 can follow the partial helical configuration 136 extending along the longitudinal central axis 112 of the frame 102 such that elongate portions 120, 122, 124, and 126 of the frame 102 maintain a planar relationship with the walls

of a body lumen. In other words, the helical twisting 136 of the frame 102 allows the planar outer surface 110 of the elongate portions 120, 122, 124, and 126 of the frame 102 to contact the wall of a body lumen in a patient.

In the various embodiments, the frame 102 can provide symmetrical relationships for the one or more elongate portions 120, 122, 124, and 126 and the vertices 111, 113, 115, and 117. For example, as illustrated in Figs. 1A-1B, 2A, and 3, the frame 102 can provide bilateral and radial symmetries, among other things. With respect to bilateral symmetry, in Fig. 1A, the second elongate portion 122 and the fourth elongate portion 126 can have a symmetrical relationship to the first elongate portion 120 and the third elongate portion 124, respectively, across a plane extending from the first common axis 138 and bisecting the second common axis 140 perpendicularly. In other words, the second elongate portion 122 and the fourth elongate portion 126 can provide a mirror image of the first elongate portion 120 and the third elongate portion 124, respectively. Similarly, the first vertex 111 and the third vertex 115 can provide mirror images of the second vertex 113 and the fourth vertex 117, respectively.

As will be appreciated, the various members and vertices of the frame 102 need not necessarily, however, display a symmetrical relationship in order to practice the embodiments of the present invention. For example, in the embodiments illustrated in Figs. 1A and 1B, the radial relationship of the first elongate portion 120 and the second elongate portion 122 can be set apart approximately ninety (90) degrees or greater relative each other around the longitudinal central axis 112 of the frame 102. In which case the first elongate portion 120 and the fourth elongate portion 122, and the second elongate portion 122 and the third elongate portion 124 can be set apart approximately ninety (90) degrees or less relative each other around the longitudinal central axis 112 of the frame 102. Other radial relationships are also possible.

Referring again to Figs. 1A, the outer diameter 142 and a length 143 of valve 100 can have a number of values. As used herein, the outer diameter can include the distance between two vertices located at the same common axis. For example, the outer diameter 142 can include the distance between the first vertex 111 and the second vertex 113, which are positioned at the first common axis 138. In addition, the length 143 can be defined as the distance between a vertex on the first common axis and a vertex on the second common axis. For example,

the length 143 of the valve 100 can include the distance between the first vertex 111, which is positioned at the first common axis 138, and the third vertex 115, which is positioned at the second common axis 140. As will be appreciated, the outer diameter 142 and the length 143 of valve 100 can each be determined based upon the location into which the valve 100 is to be implanted.

The embodiments of the frame 102 can also be constructed of one or more of a number of materials and in a variety of configurations. Generally, the frame 102 can have a closed circumference along its length. The frame can also be self-expanding. Examples of self-expanding frames include those formed from temperature-sensitive memory alloy such as those sold under the trade designator Nitinol, which can change shape at a designated temperature or temperature range. The self-expanding frames can also include those having a spring-bias. In addition, the frame 102 can have a configuration that allows the valve 100 embodiments to be radially expandable through the use of a balloon catheter.

As will be appreciated, in various embodiments, additional spring force can be imparted to the frame 102 from the compression of the partial helical configuration 136 of the frame 102 illustrated in Fig. 1B. For example, as all or a portion of the frame 102 is radially compressed towards longitudinal central axis 112, both the corner portions 119 and the partial helical configuration 136 of the frame 102 can resiliently bend (e.g., the spiral shape of the partial helical configuration is turned more tightly) to store elastic force (e.g., elastic potential energy) that allows the frame 102 to expand radially so as to return towards its uncompressed state.

The materials used in constructing frame 102 can also be pre- and/or post-treated. For example, the material characteristics of the frame can be modified by imparting to the corner portions, e.g. 119, 219, and 319, a radial arc that flares the frame outward from the longitudinal central axis. In one embodiment, the radial arc may be sufficiently large such that portions of the frame at the corners may extend beyond the outer diameter of the frame as defined by the first planar surface. Illustrations of such a radial arc, such as those described herein, can be found in co-pending U.S. Pat. App. No. 11/150,331, filed on June 10, 2005 and entitled " Venous Valve, System, and

Method" (BSCI Docket # 04-0081US, B&C Docket #201.0130001), which is incorporated herein by reference in its entirety.

As discussed above, the embodiments of the frame can also be formed from one or more elongate members 104. For example, the frame 102 shown in Figs. 1A and 1B include a single elongate member 104. In one embodiment, the single elongate member 104 can be bent around an elongate tubular mandrel to form the frame 102. The predetermined portion 107-1 and 107-2 of the elongate member 104 can be entwined to form the closed circumference of the frame and the first and second member ends 106 and 108 of the elongate member 104 can be bent perpendicularly relative to the elongate member 104 to extend radially from the outer surface 110 of the frame 102. In an alternative embodiment, methods of joining the elongate member to create the elastic region can further include, but are not limited to, welding, gluing, and fusing the frame member. The frame can also be heat set by methods known for the material(s) which forms the frame.

The frame 102 can be formed from a number of materials. For example, the frame can be formed from a biocompatible metal, metal alloy, polymeric material, or combination thereof. As discussed herein, the frame can be self-expanding or balloon expandable. In addition, the frame can be configured so as to have the ability to move radially between the collapsed state and the expanded state. To accomplish this, the material used to form the frame should exhibit an elastic modulus and a yield stress for large elastic strains that can recover from elastic deformations. Examples of suitable materials include, but are not limited to, medical grade stainless steel (e.g., 316L), titanium, tantalum, platinum alloys, niobium alloys, cobalt alloys, alginate, or combinations thereof. Additional frame embodiments may be formed from a shape-memory material, such as shape memory plastics, polymers, and thermoplastic materials which are inert in the body. Shaped memory alloys having superelastic properties generally made from ratios of nickel and titanium, commonly known as Nitinol, are also possible materials. Other materials are also possible.

As discussed herein, in various embodiments, the frame 102 can further include one or more anchoring elements. For example, the one or more anchoring elements can include, but are not limited to, the first and second

member ends 106 and 108, one or more barbs projecting obliquely from the first and second member ends 106 and 108 of the frame 102, and/or from the one or more elongate members 104 of the frame 102. The valve 100 can further include one or more radiopaque markers (e.g., tabs, sleeves, welds). For example, one or more portions of the frame 102 can be formed from a radiopaque material. Radiopaque markers can be attached to and/or coated onto one or more locations along the frame. Examples of radiopaque material include, but are not limited to, gold, tantalum, and platinum. The position of the one or more radiopaque markers can be selected so as to provide information on the position, location and orientation of the valve during its implantation.

Referring now to Figure 2A, an embodiment of a valve 200 is illustrated that includes four (4) elongate members 204-1, 204-2, 204-3, and 204-4. As shown in Fig. 2A, each of the four (4) elongate members can include the first member end 206, the second member end 208, and the predetermined portion 207-1 and 207-2 adjacent the first and the second member ends 206 and 208 respectively. As discussed herein, the predetermined portion 207-1 and 207-2 adjacent the first and the second member ends 206 and 208 entwine to form the closed circumference of the frame 202. The frame 202 can have an outer surface 210, and the first and second member ends 206 and 208 can extend radially from the outer surface 210 and from the longitudinal central axis 212 of the frame 202.

Referring now to Figure 3, an embodiment of a valve 300 is illustrated that includes eight (8) elongate members 304-1 through 304-8. As shown in Fig. 3, each elongate member can have the first member end 306, the second member end 308, and the predetermined portion 307-1 and 307-2 adjacent the first and the second member ends 306 and 308 respectively. As discussed herein, the predetermined portion 307-1 and 307-2 adjacent the first and the second member ends 306 and 308 entwine to form a closed circumference of the frame 302. The frame 302 can have an outer surface 310, and the first and second member ends 306 and 308 can extend radially from the outer surface 310 and from the longitudinal central axis 312 of the frame 302.

Referring again to Fig 1A, the cover 101 on the frame 102 can include surfaces defining a reversibly sealable opening 144 for unidirectional flow of a liquid through the valve 100. For example, the surfaces of the cover 101 can be

deflectable between a closed configuration in which fluid flow through the lumen 105 can be restricted and an open configuration in which fluid flow through the lumen 105 can be permitted.

In one embodiment, the cover 101 can be located over at least the outer surface 110 of the frame 102 so as to cover the outer surface 110 of the frame 102 except for the first and second member ends 106 and 108 that protrude outward from the cover 101. In other words, the cover 101 extends over the outer surface 110 of the frame 102 so that the exposed portions of the outer surface 110 of the frame 102 are limited, or eliminated, except for the first and second member ends 106 and 108.

In an additional example, the cover 101 can extend between each of the elongate portions 120, 122, 124, and 126 and vertices 111, 113, 115 and 117 to completely surround the circumference of the frame 102. In an additional embodiment, the cover 101 can be located over at least an inner surface 130 of the frame 102. A further embodiment includes the cover 101 located over at least the outer surface 110 and the inner surface 130.

Figs. 5A-5D illustrate an additional embodiment of the venous valve 500. Figs. 5A and 5B provide a perspective illustration of valve 500 in an open configuration (Fig. 5A) and a closed configuration (Fig. 5B). Figs. 5C and 5D provide a sectional view taken along cut lines 5C-5C and 5D-5D shown in Figs. 5A and 5B, respectively, to more clearly illustrate the embodiment of the venous valve 500.

As discussed herein, cover 501 includes surfaces defining the reversibly sealable opening 544 for unidirectional flow of a liquid through the lumen 505. In the embodiment illustrated in Figs. 5A and 5B, the cover 501 extends over at least a portion of the frame 502 to a first connection point 546 proximal the third vertex 515 and a second connection point 548 proximal the fourth vertex 517 on the frame 502, as the same have been described and illustrated in connection with Figs. 1 and 2. In one example, the first connection point 546 and the second connection point 548 can be located at the third vertex 515 and the fourth vertex 517 of the frame 502. The cover 501 extends between the first connection point 546 and the second connection point 548 to provide a first valve leaflet 550 and a second valve leaflet 552. The first valve leaflet 550 and the second valve

leaflet 552 can form the reversibly sealable opening 544 extending between the first connection point 546 and the second connection point 548. Thus, in the embodiment shown in Fig. 5A the first valve leaflet 550 and the second valve leaflet 552 form the reversibly sealable opening 544 extending between the third vertex 515 and the fourth vertex 517 of the frame 502.

As illustrated, the first valve leaflet 550 and the second valve leaflet 552 include a region 554 of the cover 501 that can move relative the frame 502. The region 554 of the cover 501 can be unbound (i.e., unsupported) by the frame 502 and extends between the first connection point 546 and the second connection point 548 of the valve 500. This configuration permits the reversibly sealable opening 544 to open and close in response to the fluid pressure differential across the valve leaflets 550 and 552.

For example, under antegrade fluid flow (i.e., positive fluid pressure) from the first end 514 towards the second end 516 of the valve 500, the first and second valve leaflets 550 and 552 can expand toward the inner surface 530 to create an opening through which fluid is permitted to move. In one example, the first valve leaflet 550 and the second valve leaflet 552 can each expand to define a semi-tubular structure when fluid opens the reversibly sealable opening 544. An example of the open configuration for the valve is shown in Figs. 5A and 5C.

Under a retrograde fluid flow (i.e., negative fluid pressure) from the second end 516 towards the first end 514, the first and second valve leaflets 550 and 552 can move away from the inner surface 530 as the valve leaflets 550 and 552 begin to close valve 500. In one example, a pocket 556 exists between the frame 502 and each of the first and second valve leaflets 550 and 552. The pocket 556 allows fluid from the retrograde flow to develop pressure on a first major face 558 of the first and second valve leaflets 550 and 552, for example, as illustrated in Fig. 5B. In one embodiment, an example of a pocket 556 is illustrated in co-pending U.S. Pat. App. No. 11/150,331, filed on June 10, 2005 and entitled " Venous Valve Frame, System, and Method" (BSCI Docket # 04-0081US, B&C Docket #201.0130001), which is incorporated herein by reference in its entirety.

As fluid pressure develops, the first and second valve leaflets 550 and 552 collapse, closing the reversibly sealable opening 544 to create a seal 555,

thereby restricting retrograde fluid flow through the valve 500. In one example, the seal 555 can be created by the joining of a sealing surface 566 of the first and second valve leaflets 550 and 552, for example as illustrated in Fig. 5C. In the closed configuration, the first and second valve leaflets 550 and 552 can each have a concave structure when fluid closes the reversibly sealable opening 544. An example of a closed configuration for the valve is shown in Figs. 5B and 5D.

In one embodiment, each of the first valve leaflet 550 and the second valve leaflet 552 includes sufficient excess material spanning frame 502 such that fluid pressure (e.g., antegrade flow) acting on a second major surface 560 of the first valve leaflet 550 and the second valve leaflet 552 forces the valve 500 into an open configuration.

As discussed above, the elastic regions of the frame also allow valve to elastically and repeatably travel between a collapsed state and an expanded state. For example, in the embodiments shown in Figs. 6A and 6B, the valve 600 is illustrated in a collapsed state (Fig. 6A) and in an expanded state (Fig. 6B). As shown in Figs. 6A and 6B, the valve 600 can travel between the collapsed and the expanded state along a radial travel path 661 (as shown in Fig. 6B), where there can be a change in a cross sectional area 663 of lumen 605. For example, the valve frame 602 can travel along the radial travel path 661 so as to change a width 665 of lumen 605. This can allow the valve 600 to react appropriately to the distension and contraction of a body lumen in which the valve 600 is placed.

In addition to the illustrated corner portions 119, the elastic regions can further include, but are not limited to, other shapes for the valve frame 102 that allow for repeatable travel between the collapsed state and the expanded state. For example, the elastic regions can include integrated springs having a circular or an elliptical loop configuration. Other shapes are also possible.

Referring again to Figs. 1A-1B, valve 100 provides an embodiment in which the surfaces defining the reversibly sealable opening 144 provide a bi-leaflet configuration (i.e., a bicuspid valve) for valve 100. Although the embodiments described herein illustrate and describe a bi-leaflet configuration for the valve of the present invention, designs employing a different number of valve leaflets (e.g., tri-leaflet valve) are possible. For example, additional connection points (e.g., three or more) could be used to provide additional valve leaflets (e.g., a tri-leaflet valve).

The first valve leaflet 150 and the second valve leaflet 152 can have a variety of sizes and shapes. In one embodiment, each of the first valve leaflet 150 and the second valve leaflet 152 can have a similar size and shape. In other embodiments, each of the first valve leaflet 150 and the second valve leaflet 152 need not have a similar size and shape (i.e., the valve leaflets can have a different size and shape with respect to each other).

The first valve leaflet 150 and the second valve leaflet 152 each further include an arcuate edge 167 positioned adjacent each other along a substantially catenary curve between the connection point 146 and the second connection point 148 in the closed configuration of valve 100. Similarly, the arcuate edge 167 can define opening 144 when the valve 100 is in the open configuration. In one embodiment, the extent of the arcuate edge 167 imparted to the valve leaflet 150 and/or 152 can depend upon the elasticity of the material used for the valve leaflets. This aspect is illustrated in co-pending U.S. Pat. App. No. 11/150,331, entitled " Venous Valve Frame, System, and Method" (BSCI Docket # 04-0081US, B&C Docket #201.0130001), which is incorporated herein by reference in its entirety.

In an additional embodiment, in the open configuration the portion of the cover 101 forming the first valve leaflet 150 and the second valve leaflet 152 provides sufficient excess material spanning between the first connection point 146 and the second connection point 148 to allow the first and second major surfaces 158 and 160 to take on a semi-tubular structure 145, as shown in Fig. 1A, when fluid pressure opens the valve 100. In an additional embodiment, the arcuate edges 167 of valve 100 can open to approximately the full inner diameter of a body lumen. In an alternative embodiment, the arcuate edges 167 of valve 100 can open to provide a gap, or a space, between the arcuate edges 167 of valve 100 and the inner diameter of a body lumen. This aspect is illustrated in co-pending U.S. Pat. App. No. 11/150,331, entitled " Venous Valve Frame, System, and Method" (BSCI Docket # 04-0081US, B&C Docket #201.0130001), which is incorporated herein by reference in its entirety.

Each of the second major surfaces 160 of the first valve leaflet 150 and the second valve leaflet 152 can further include a curve imparted thereto so as to provide the first major surface 158 with the pocket (illustrated as 556 in Figure 5B). The pocket allows the first valve leaflet 150 and the second valve leaflet

152 to better collect retrograde fluid flow to urge the first valve leaflet 150 and the second valve leaflet 152 towards the closed configuration. For example, as retrograde flow begins, the first valve leaflet 150 and the second valve leaflet 152 respond by moving towards the center (e.g., towards 112) of valve 100. As the first valve leaflet 150 and the second valve leaflet 152 approach the center of the device the sealing surfaces 166 make sufficient contact to effectively close valve 100 and restrict retrograde fluid flow.

In an additional embodiment, the first valve leaflet 150 and the second valve leaflet 152 can include one or more support structures, where the support structures can be integrated into and/or onto the valve leaflets 150 and 152. For example, the first valve leaflet 150 and the second valve leaflet 152 can include one or more support ribs, as the same will be known and understood, having a predetermined shape. In one embodiment, the predetermined shape of the support ribs can include a curved bias so as to provide the first valve leaflet 150 and the second valve leaflet 152 with a curved configuration. Support ribs can be constructed of a flexible material and have dimensions (e.g., thickness, width and length) and cross-sectional shape that allows the support ribs to be flexible when the first valve leaflet 150 and the second valve leaflet 152 are urged into an open position, and stiff when the first valve leaflet 150 and the second valve leaflet 152 are urged into a closed position upon experiencing sufficient back flow pressure from the direction downstream from the valve. In an additional embodiment, support ribs can also be attached to valve frame 102 so as to impart a spring bias to the valve leaflets in either the open or the closed configuration.

In one embodiment, the material of the first valve leaflet 150 and the second valve leaflet 152 can be sufficiently thin and pliable so as to permit radially-collapsing of the valve leaflets for delivery by catheter to a location within a body lumen. The first valve leaflet 150 and the second valve leaflet 152 can be constructed of a fluid-impermeable biocompatible material that can be either synthetic or biologic. Possible synthetic materials include, but are not limited to, expanded polytetrafluoroethylene (ePTFE), polytetrafluoroethylene (PTFE), polystyrene-polyisobutylene-polystyrene (SIBS), polyurethane, segmented poly(carbonate-urethane), Dacron, polyethlylene (PE), polyethylene terephthalate (PET), silk, urethane, Rayon, Silicone, or the like. Possible biologic materials include, but are not limited to, autologous, allogeneic or

xenograft material. These include explanted veins and decellularized basement membrane materials, such as small intestine submucosa (SIS) or umbilical vein.

As discussed herein, the cover 101 can be located over at least the outer surface 110 of the frame 102. In an additional embodiment, the cover 101 can also be located over at least the inner surface 130 of the frame 102, where the cover 101 can be joined to itself in the area between the elongate portions (e.g., between first elongate portion 120 and third elongate portion 124, and second elongate portion 122 and fourth elongate portion 126) so as to fully or partially encase the frame 102. Numerous techniques may be employed to laminate or bond cover 101 on the outer surface 110 and/or the inner surface 130 of the frame 102, including heat setting, adhesive welding, application of uniform force and other bonding techniques. Additionally, the cover 101 may be folded over the second end 116 of the frame 102 to provide the cover 101 on both the outer surface 110 and the inner surface 130. Cover 101 can also be joined to itself and/or the members according to the methods described in U. S. Patent Application Publication US 2002/0178570 to Sogard et al., which is hereby incorporated by reference in its entirety.

The cover 101 can also be coupled to the connection points so as to form the valve leaflets, as discussed herein. In one embodiment, the cover 101 can be in the form of a sheet or a sleeve of material, as discussed herein, which can be connected to the frame 102. Alternatively, the cover 101 can initially be in the form of a liquid that can be used to cast and/or form the cover over the frame 102. Other forms, including intermediate forms, of the cover 101 are also possible.

The cover 101 can be coupled to the frame 102, including the connection points 146 and 148, in a variety of ways so as to provide the various embodiments of the valve of the present invention. For example, a variety of fasteners can be used to couple the cover 101 to the frame 102 so as to form the valve 100. Suitable fasteners can include, but are not limited to, biocompatible staples, glues, sutures or combinations thereof. In an additional embodiment, the cover 101 can be coupled to the frame 102 through the use of heat sealing, solvent bonding, adhesive bonding, or welding cover 101 to either a portion of the cover 101 (i.e., itself) and/or the frame 102.

The cover 101, including the valve leaflets 150 and 152, may also be treated and/or coated with a number of surface or material treatments. For example, the cover 101 can be treated with one or more biologically active compounds and/or materials that may promote and/or inhibit endothelization and/or smooth muscle cell growth of the cover 101, including the valve leaflets 150 and 152. Similarly, the cover 101 may be seeded and covered with cultured tissue cells (e.g., endothelial cells) derived from a either a donor or the host patient which are attached to the valve leaflets 150 and 152. The cultured tissue cells may be initially positioned to extend either partially or fully over the valve leaflets 150 and 152.

Cover 101, in addition to forming valve leaflets 150 and 152, can also be capable of inhibiting thrombus formation. Additionally, cover 101 may either prevent or facilitate tissue ingrowth therethrough, as the particular application for the valve 100 may dictate. For example, cover 101 on the outer surface 162 may be formed from a porous material to facilitate tissue ingrowth therethrough, while cover 101 on the inner surface 164 may be formed from a material or a treated material which inhibits tissue ingrowth.

Fig. 7 illustrates one embodiment of a system 770. System 770 includes valve 700, as described herein, reversibly joined to catheter 772. The catheter 772 includes an elongate body 774 having a proximal end 776 and a distal end 778, where valve 700 can be located between the proximal end 776 and distal end 778. The catheter 772 can further include a lumen 784 longitudinally extending to the distal end 778. In one embodiment, lumen 784 extends between proximal end 776 and distal end 778 of catheter 782. The catheter 782 can further include a guidewire lumen 780 that extends within the elongate body 774, where the guidewire lumen 780 can receive a guidewire for positioning the catheter 782 and the valve 700 within a body lumen (e.g., a vein of a patient).

The system 770 can further include a deployment shaft 782 positioned within lumen 784, and a sheath 786 positioned adjacent the distal end 778. In one embodiment, the valve 700 can be positioned at least partially within the sheath 786 and adjacent the deployment shaft 782. The deployment shaft 782 can be moved within the lumen 784 to deploy valve 700. For example, deployment shaft 782 can be used to push valve 700 from sheath 786 in deploying valve 700.

Fig. 8 illustrates an additional embodiment of the system 870. The catheter 872 includes elongate body 874, lumen 884, a retraction system 888 and a retractable sheath 889. The retractable sheath 889 can be positioned over at least a portion of the elongate body 874, where the retractable sheath 889 can move longitudinally along the elongate body 874. The valve 800 can be positioned at least partially within the retractable sheath 889, where the retractable sheath 889 moves along the elongate body 874 to deploy the valve 800. In one embodiment, retraction system 888 includes one or more wires 895 coupled to the retractable sheath 889, where the wires are positioned at least partially within and extend through lumen 884 in the elongate body 874. Wires of the retraction system 888 can then be used to retract the retractable sheath 889 in deploying valve 800.

Fig. 9 illustrates an additional embodiment of the system 970. The catheter 972 includes elongate body 974, an inflatable balloon 990 positioned adjacent the distal end 978, and a lumen 992 longitudinally extending in the elongate body 974 of the catheter 972 from the inflatable balloon 990 to the proximal end 976. In the present example, the inflatable balloon 990 can be at least partially positioned within the lumen 905 of the valve 900. The inflatable balloon 990 can be inflated through the lumen 992 to deploy the valve 900.

The embodiments of the present invention further include methods for forming the valve of the present invention, as discussed herein. For example, the valve can be formed from the frame and the cover over at least the outer surface of the frame, where the cover includes surfaces defining the reversibly sealable opening for unidirectional flow of a liquid through the lumen. In an additional example, the valve can be reversibly joined to the catheter, which can include a process of altering the shape of the valve from a first shape, for example an expanded state, to the compressed state, as described herein.

For example, the valve can be reversibly joined with the catheter by positioning valve in the compressed state at least partially within the sheath of the catheter. In one embodiment, positioning the valve at least partially within the sheath of the catheter includes positioning the valve in the compressed state adjacent the deployment shaft of the catheter. In an another embodiment, the sheath of the catheter functions as a retractable sheath, where the valve in the compressed state can be reversibly joined with the catheter by positioning the

valve at least partially within the reversible sheath of the catheter. In a further embodiment, the catheter can include an inflatable balloon, where the balloon can be positioned at least partially within the lumen of the valve, for example, in its compressed state.

The embodiments of the valve described herein may be used to replace, supplement, or augment valve structures within one or more lumens of the body. For example, embodiments of the present invention may be used to replace an incompetent venous valve and help to decrease backflow of blood in the venous system of the legs.

In one embodiment, the method of replacing, supplementing, and/or augmenting a valve structure can include positioning at least part of the catheter including the valve at a predetermined location within the lumen of a body. For example, the predetermined location can include a position within a body lumen of a venous system of a patient, such as a vein of a leg.

In one embodiment, positioning the catheter that includes the valve within the body lumen of a venous system includes introducing the catheter into the venous system of the patient using minimally invasive percutaneous, transluminal catheter based delivery system, as is known in the art. For example, a guidewire can be positioned within a body lumen of a patient that includes the predetermined location. The catheter, including valve, as described herein, can be positioned over the guidewire and the catheter advanced so as to position the valve at or adjacent the predetermined location. In one embodiment, radiopaque markers on the catheter and/or the valve, as described herein, can be used to help locate and position the valve. For example, embodiments for positioning radiopaque markers on the catheter and/or the valve can be found in co-pending U.S. Pat. App. No. 11/150,331, filed on June 10, 2005 and entitled "Venous Valve Frame, System, and Method" (BSCI Docket # 04-0081US, B&C Docket #201.0130001), which is incorporated herein by reference in its entirety.

The valve can be deployed from the catheter at the predetermined location in a number of ways, as described herein. In one embodiment, valve of the present invention can be deployed and placed in a number of vascular locations. For example, valve can be deployed and placed within a major vein of a patient's leg. In one embodiment, major veins include, but are not limited to, those of the peripheral venous system. Examples of veins in the peripheral

venous system include, but are not limited to, the superficial veins such as the short saphenous vein and the greater saphenous vein, and the veins of the deep venous system, such as the popliteal vein and the femoral vein.

As discussed herein, the valve can be deployed from the catheter in a number of ways. For example, the catheter can include the retractable sheath in which valve can be at least partially housed, as discussed herein. Valve can be deployed by retracting the retractable sheath of the catheter, where the valve self-expands to be positioned at the predetermined location. In an additional example, the catheter can include a deployment shaft and sheath in which valve can be at least partially housed adjacent the deployment shaft, as discussed herein. Valve can be deployed by moving the deployment shaft through the catheter to deploy valve from the sheath, where the valve self-expands to be positioned at the predetermined location. In an additional embodiment, the valve can be deployed through the use of an inflatable balloon.

Once implanted, the valve can provide sufficient contact and expansion force against the body lumen wall to prevent retrograde flow between the valve and the body lumen wall. For example, the valve can be selected to have a larger expansion diameter than the diameter of the inner wall of the body lumen. This can then allow valve to exert a force on the body lumen wall and accommodate changes in the body lumen diameter, while maintaining the proper placement of valve. As described herein, the valve can engage the lumen so as to reduce the volume of retrograde flow through and around valve. It is, however, understood that some leaking or fluid flow may occur between the valve and the body lumen and/or through valve leaflets.

While the present invention has been shown and described in detail above, it will be clear to the person skilled in the art that changes and modifications may be made without departing from the scope of the invention. As such, that which is set forth in the foregoing description and accompanying drawings is offered by way of illustration only and not as a limitation. The actual scope of the invention is intended to be defined by the following claims, along with the full range of equivalents to which such claims are entitled.

In addition, one of ordinary skill in the art will appreciate upon reading and understanding this disclosure that other variations for the invention described herein can be included within the scope of the present invention. For

example, the frame 102 and/or the cover 101 can be coated with a non-thrombogenic biocompatible material, as are known or will be known.

In the foregoing Detailed Description, various features are grouped together in several embodiments for the purpose of streamlining the disclosure. This method of disclosure is not to be interpreted as reflecting an intention that the embodiments of the invention require more features than are expressly recited in each claim. Rather, as the following claims reflect, inventive subject matter lies in less than all features of a single disclosed embodiment. Thus, the following claims are hereby incorporated into the Detailed Description, with each claim standing on its own as a separate embodiment.

WHAT IS CLAIMED IS:

1. A valve system, comprising:

a venous valve, comprising:

a frame including an elongate member having a first member end, a second member end, and a predetermined portion adjacent the first and the second member ends, where the predetermined portion adjacent the first and the second member ends entwine to form a closed circumference of the frame, and where the first and second member ends extend radially from an outer surface of the frame; and

a cover on the frame, where the cover includes surfaces defining a reversibly sealable opening for unidirectional flow of a liquid through the valve.

2. The valve system of claim 1, where the frame includes a first vertex and a second vertex relative a first end of the frame, where the first vertex and the second vertex are positioned opposite each other along a first axis.

3. The valve system of claim 2, where the cover extends to at least the first vertex and the second vertex to form a first valve leaflet and a second valve leaflet between the first vertex and the second vertex.

4. The valve system of claim 3, where the first valve leaflet and the second valve leaflet form the reversibly sealable opening extending between the first vertex and the second vertex.

5. The valve system of claim 2, where the frame includes a third vertex and a fourth vertex at the first end of the frame relative the first and second vertex, the third vertex and the fourth vertex positioned opposite each other along a second axis.

6. The valve system of claim 5, where the first, second, third, and fourth vertexes impart a radial expansion force when the frame is radially compressed.

7. The valve system of claim 1, where the predetermined portion includes a cross- sectional geometry different than a cross-sectional geometry of other portions of the frame.

8. The valve system of claim 7, where the predetermined portion includes a width different than the width of other portions of the frame, such that when the predetermined portion is entwined the width of the entwined predetermined portion equals the width of the other portions of the frame.

9. The valve system of claim 1, where the cover on the frame includes the cover over an outer surface of the frame.

10. The valve system of claim 1, where the radial extension of the first and second member ends include a barb.

11. The valve system of claim 1, where the frame includes a plurality of elongate members, each elongate member having a first member end, a second member end, and a predetermined portion adjacent the first and the second member ends, where the predetermined portion adjacent the first and the second member ends entwine to form a closed circumference of the frame, and where the first and second member ends extend radially from an outer surface of the frame.

12. The valve system of claim 11, where the plurality of elongate members of the frame include four elongate members.

13. The valve system of claim 11, where the plurality of elongate members of the frame include eight elongate members.

14. The valve system of claim 11, further comprising:

a catheter including a proximal end and a distal end, where the venous valve is located between the proximal end and the distal end.

15. The valve system of claim 14, where the catheter includes an elongate body having a lumen longitudinally extending to the distal end, a deployment shaft positioned within the lumen, and a sheath positioned adjacent the distal end, the venous valve positioned at least partially within the sheath and adjacent the deployment shaft, where the deployment shaft moves within the lumen to deploy the venous valve.

16. The valve system of claim 14, where the catheter includes an elongate body and a retractable sheath over at least a portion of the elongate body, the venous valve positioned at least partially within the retractable sheath, where the retractable sheath moves along the elongate body to deploy the venous valve.

17. The valve system of claim 14, where the catheter includes an inflatable balloon positioned adjacent the distal end and a lumen longitudinally extending in an elongate body of the catheter from the inflatable balloon to the distal end, the inflatable balloon at least partially positioned within a lumen of the venous valve, where the inflatable balloon inflates to deploy the venous valve.

18. The valve system of claim 14, where the cover extends over at least a portion of an inner surface of the frame, where the cover over the at least the portion of the inner surface extends to at least a first connection point and a second connection point on the frame to form a first valve leaflet and a second valve leaflet, where the first valve leaflet and the second valve leaflet includes a surface defining a reversibly sealable opening for unidirectional flow of a liquid through the valve.

19. A method of forming a valve system, comprising:

forming a venous valve, comprising:

providing a plurality of elongate members, each elongate member having a first member end, a second member end, and a predetermined portion adjacent the first and the second member ends;

entwining the predetermined portion of each elongate member with one another to form a closed circumference of a frame:

extending the first and second member ends radially from an outer surface of the frame; and

providing a cover on the frame, where the cover includes surfaces defining a reversibly sealable opening for unidirectional flow of a liquid through the valve.

20. The method of claim 19, further comprising reversibly joining the venous valve and the catheter.

21. The method of claim 20, where reversibly joining the venous valve and the catheter includes positioning the venous valve at least partially within a sheath of the catheter.

22. The method of claim 21, including deploying the venous valve from the catheter includes retracting a sheath of the catheter.

23. The method of claim 21, where positioning the venous valve at least partially within a sheath of the catheter includes positioning the venous valve adjacent a deployment shaft of the catheter.

24. The method of claim 23, where deploying the venous valve from the catheter includes moving the deployment shaft to deploy the venous valve from the sheath of the catheter.

25. The method of claim 19, where forming the venous valve includes:

providing the valve with a first vertex and a second vertex relative a first end of the frame and positioned opposite each other along a common axis; and

positioning the cover on the frame to extend to at least the first vertex and the second vertex to form a first valve leaflet and a second valve leaflet between the first vertex and the second vertex, where the first valve leaflet and

the second valve leaflet form the reversibly sealable opening extending between the first vertex and the second vertex.

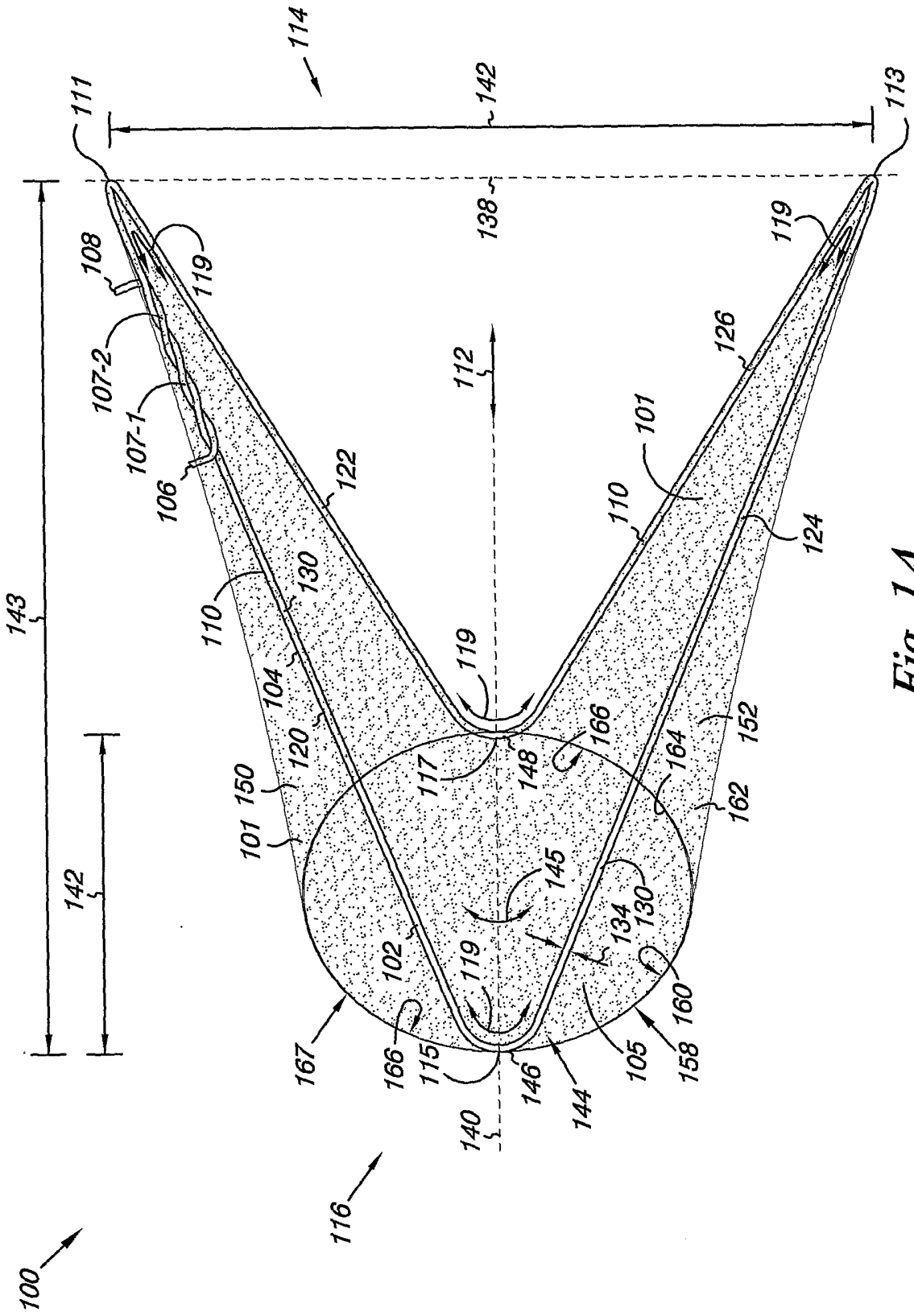
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Fig. 1A

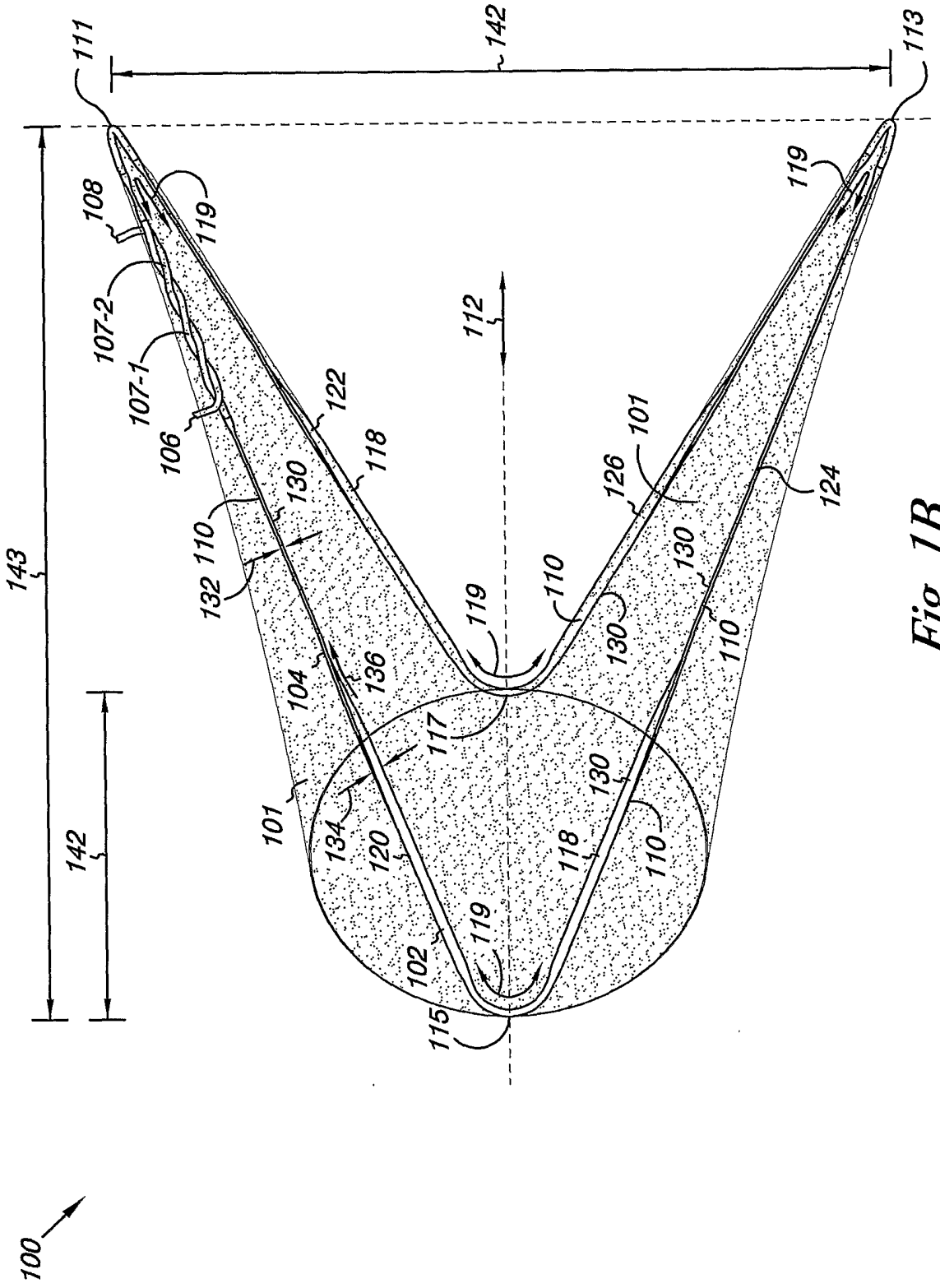
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Fig. 1B

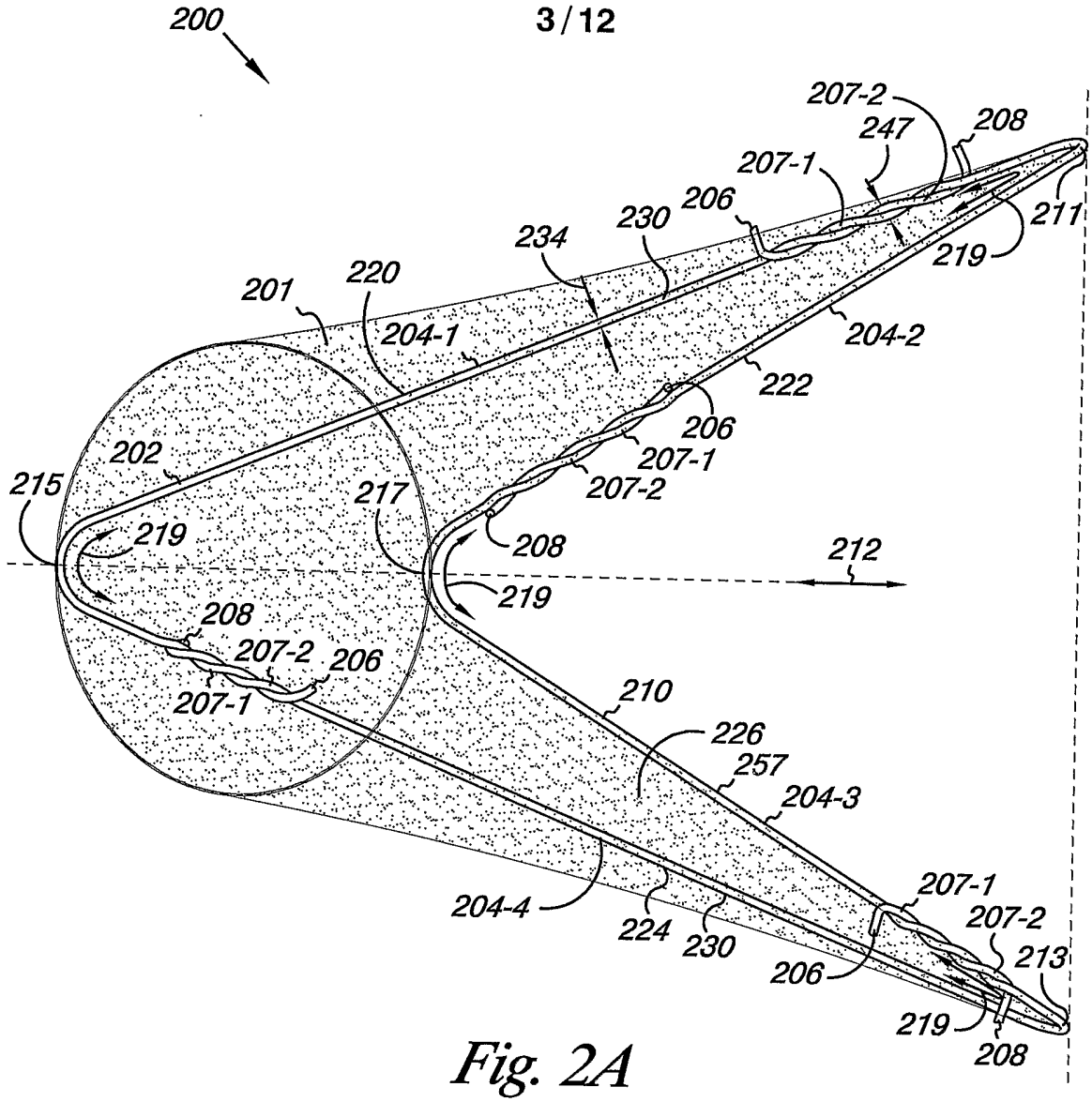
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Fig. 2A

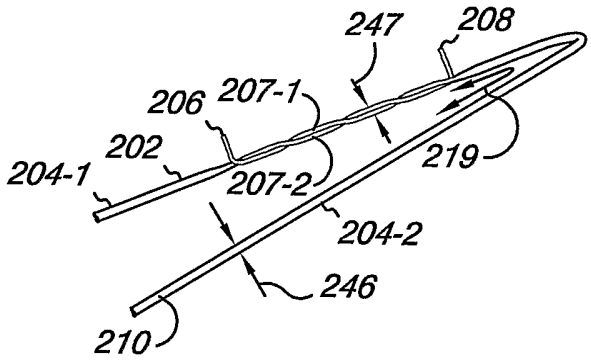
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Fig. 2B

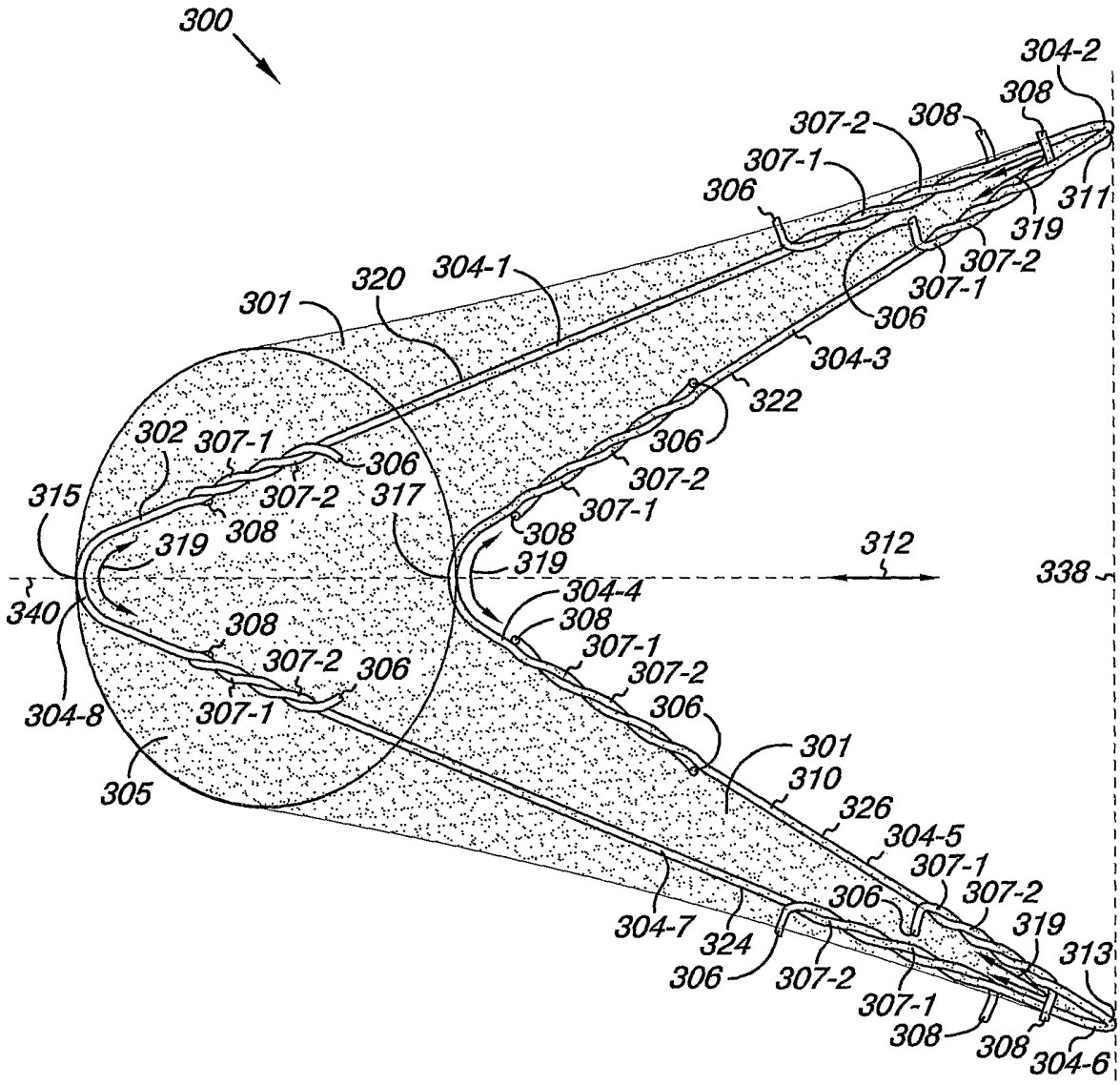
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Fig. 3

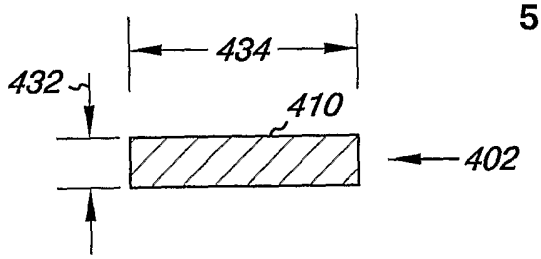

Fig. 4A

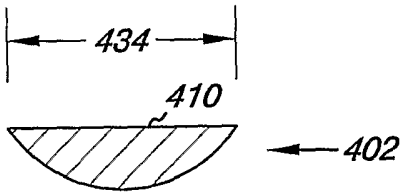

Fig. 4B

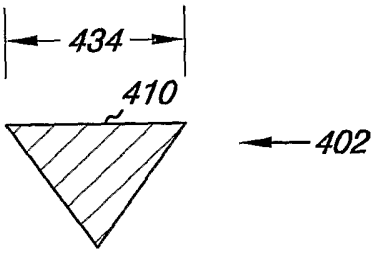

Fig. 4C

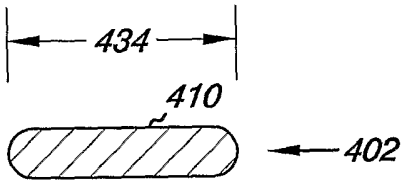

Fig. 4D

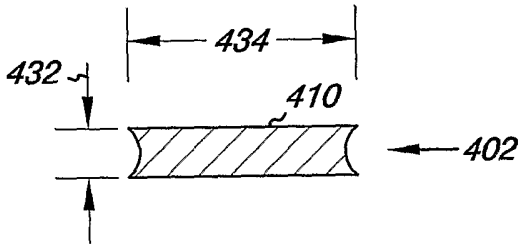

Fig. 4E

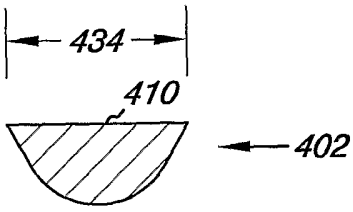

Fig. 4F

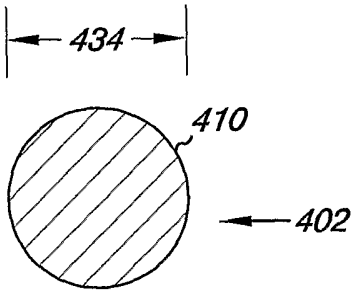

Fig. 4G

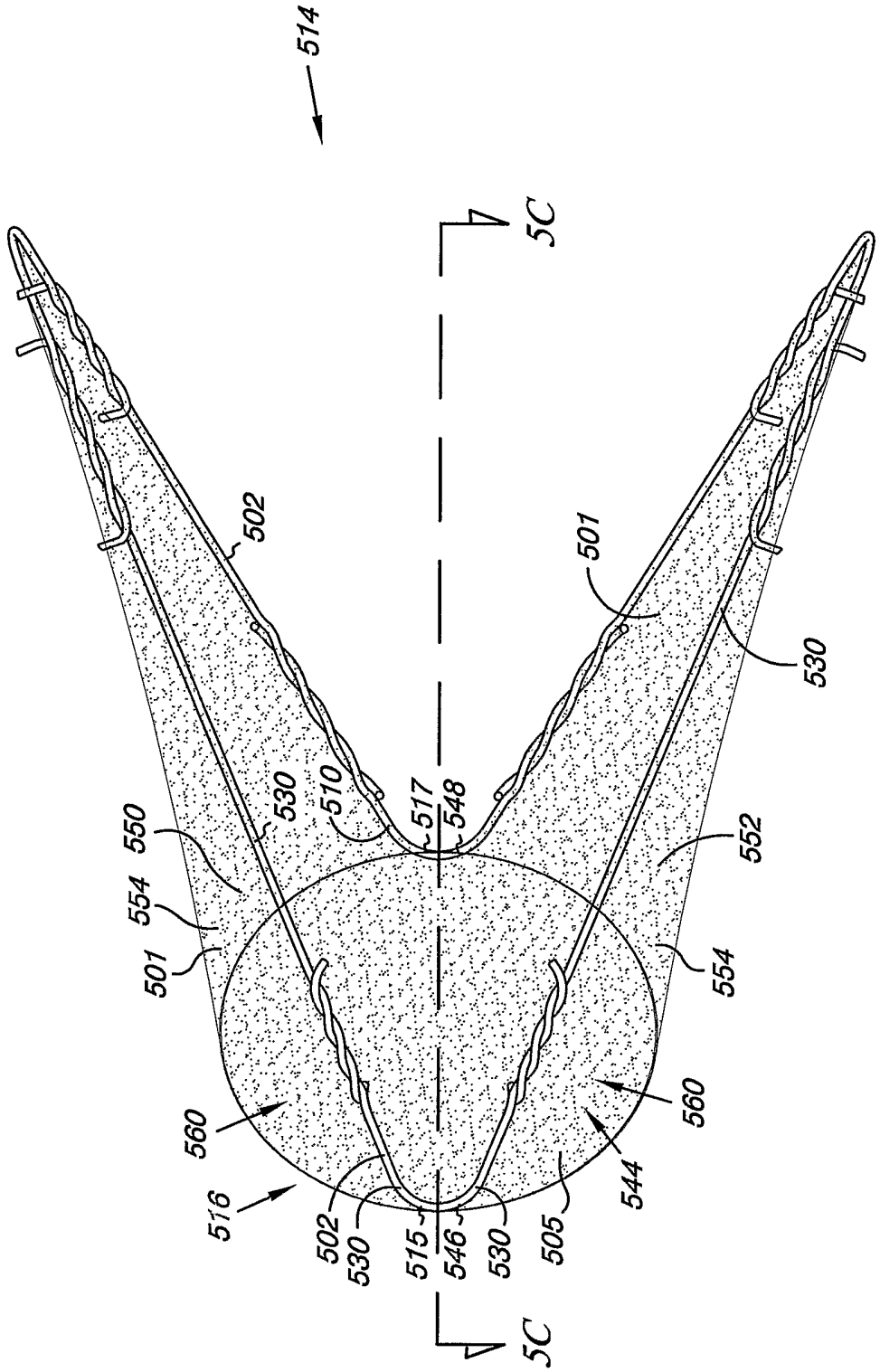
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Fig. 5A

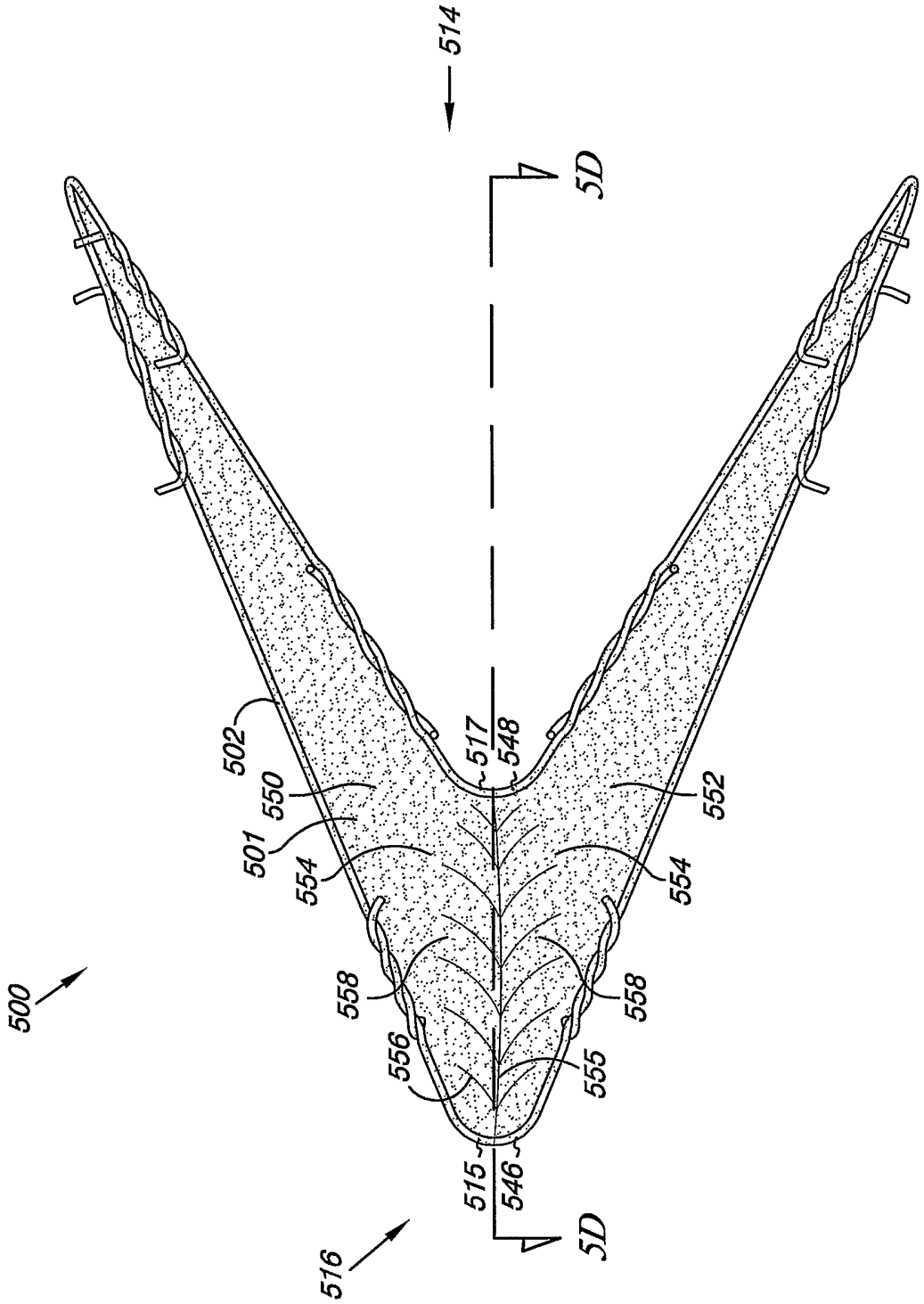
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Fig. 5B

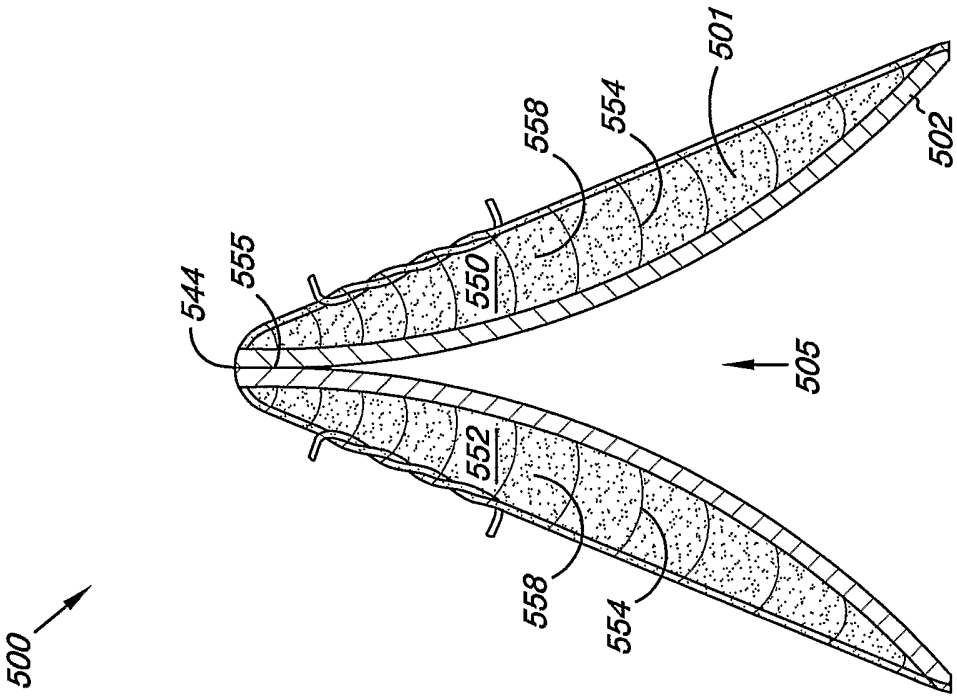
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Fig. 5D

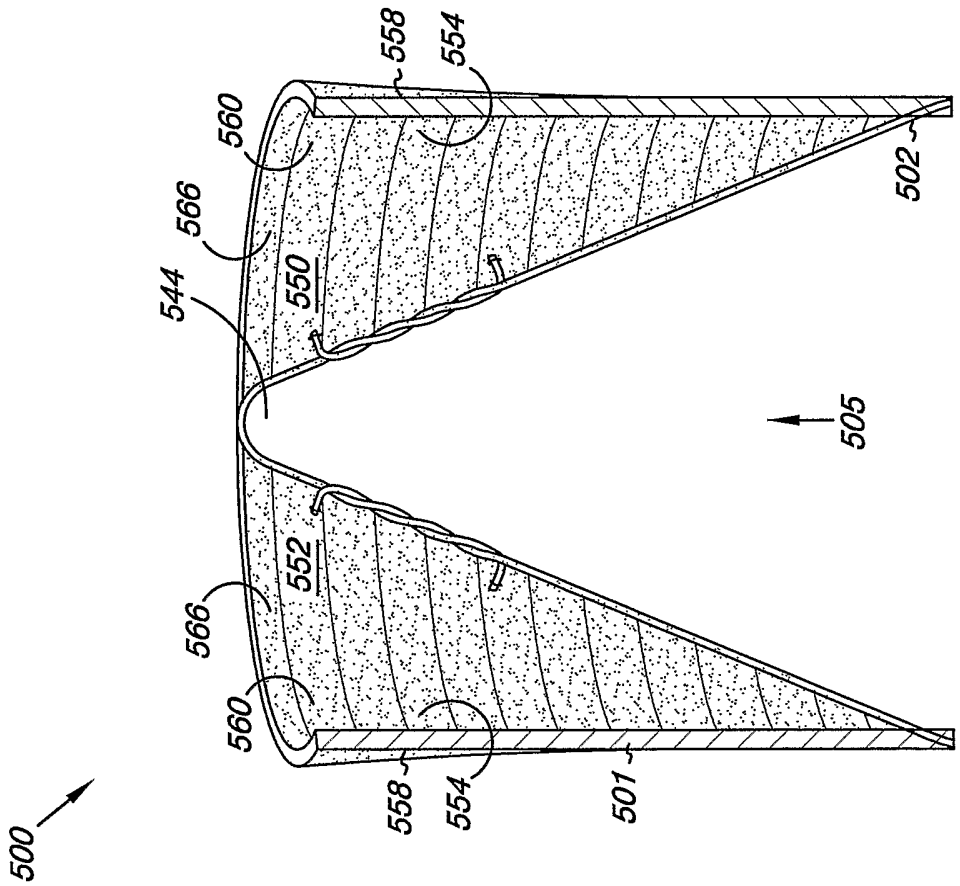
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Fig. 5C

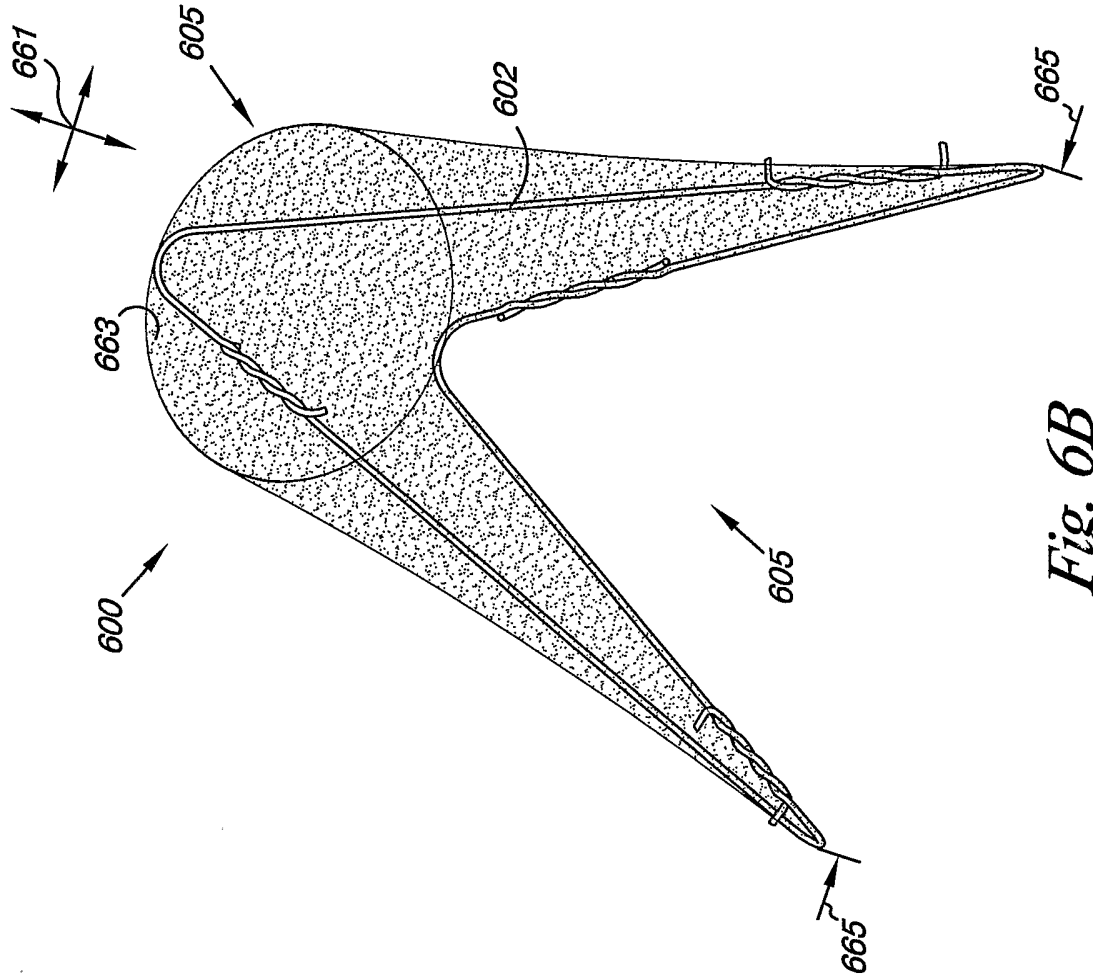

Fig. 6B

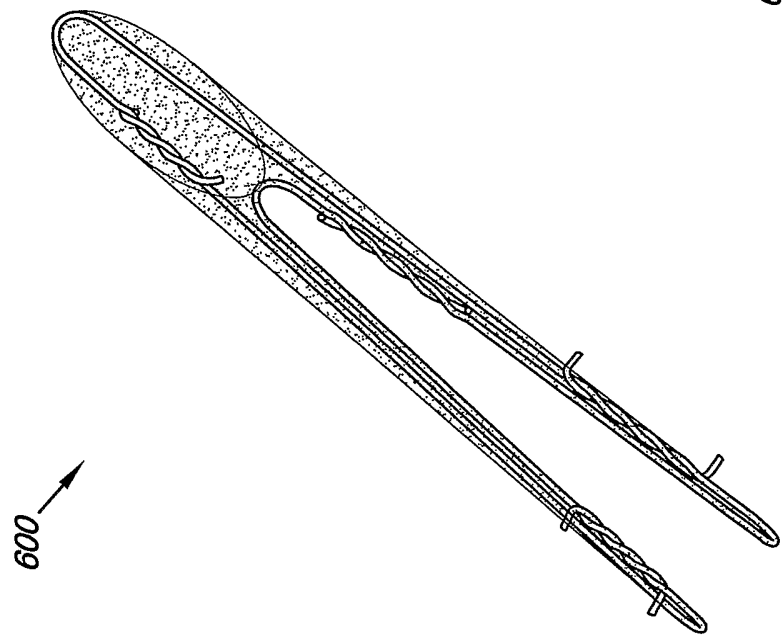

Fig. 6A

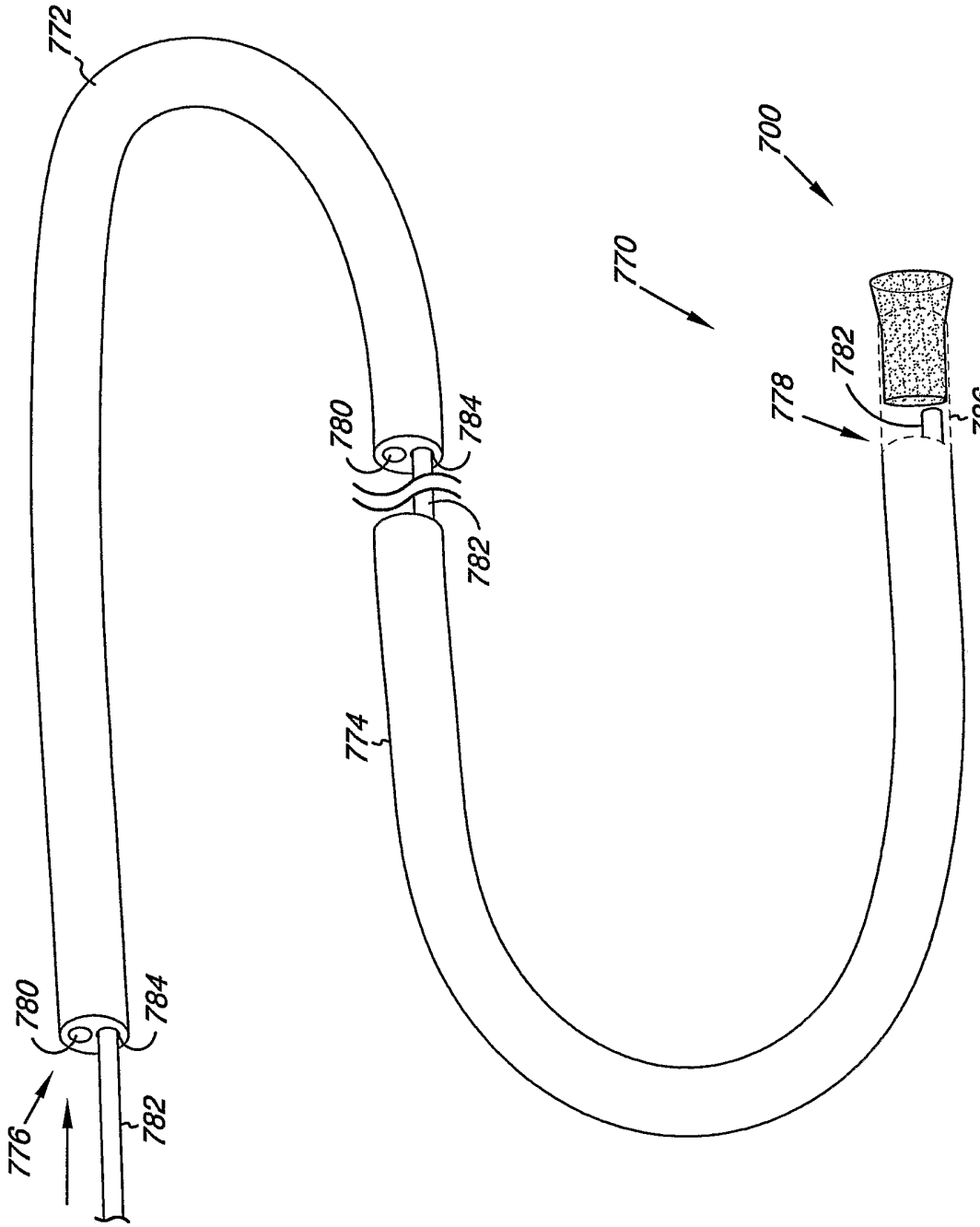

Fig. 7

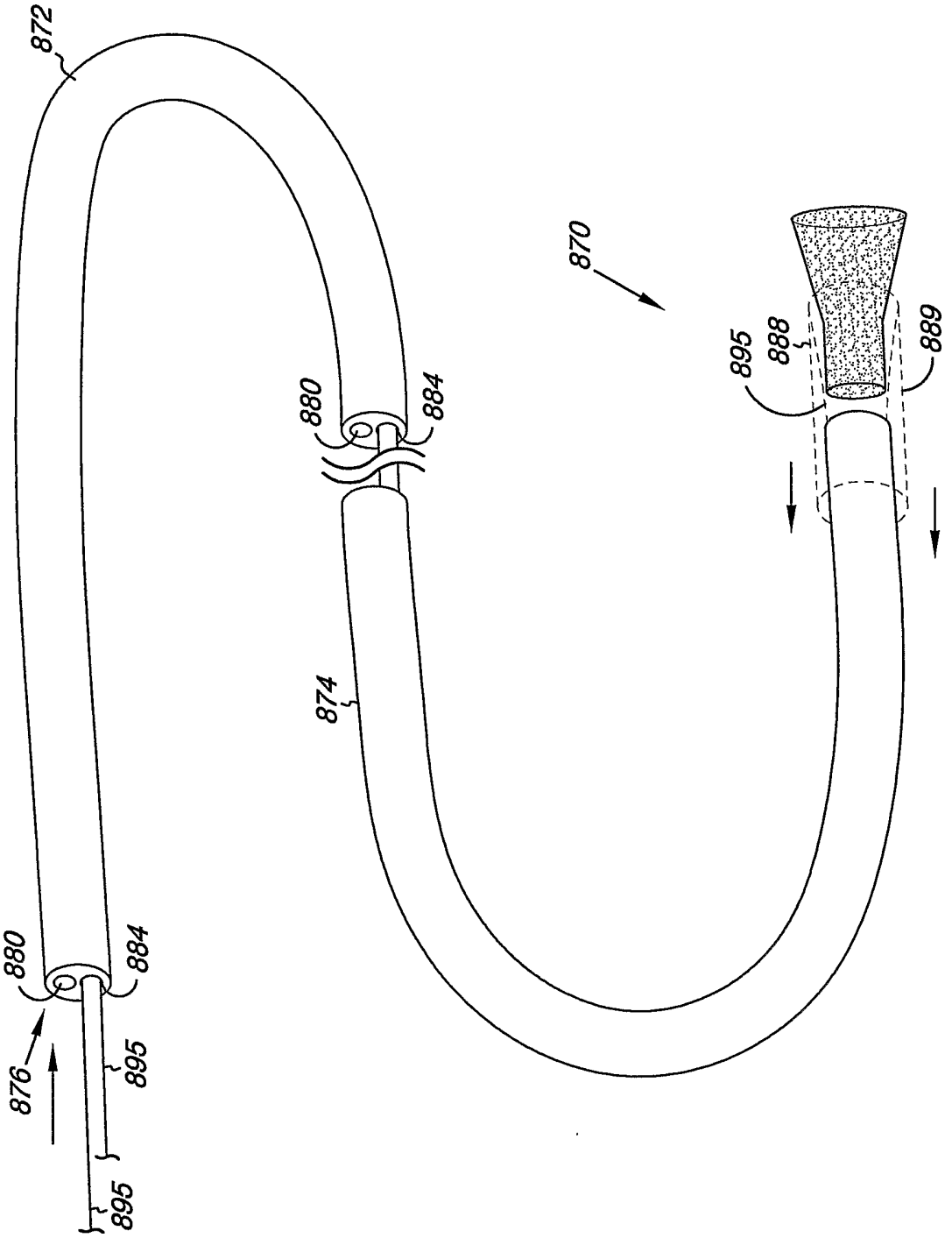

Fig. 8

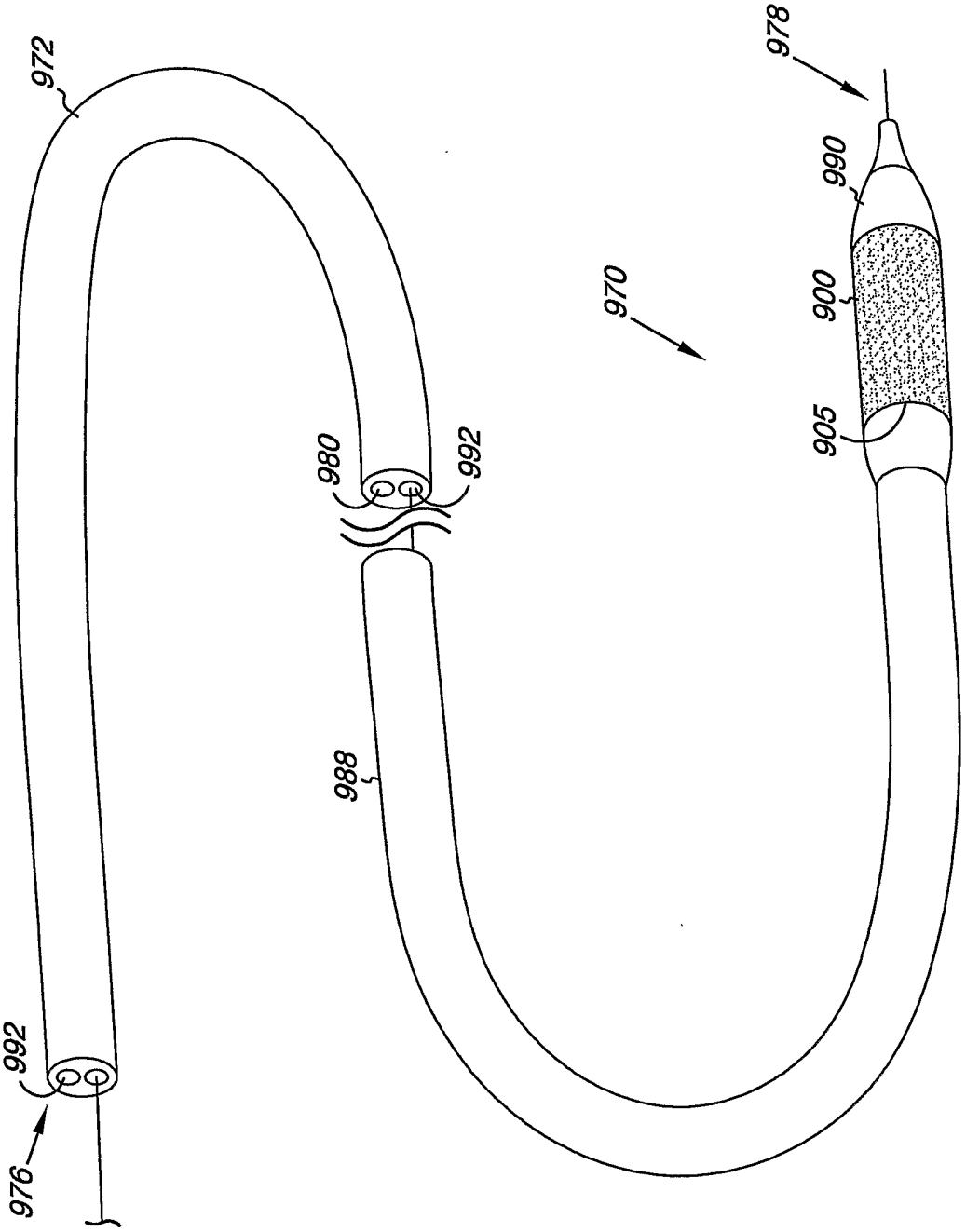

Fig. 9

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2006/000304

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/24
ADD. A61F2/02

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2004/117004 A1 (OSBORNE THOMAS A ET AL) 17 June 2004 (2004-06-17)	1-14, 18-21, 23,25
Y	paragraphs [0138], [0139], [0183], [0189], [0221]; figures 3,4,95	1-14, 18-21, 23,25
Y	US 2003/149475 A1 (HYODOH HIDEKI ET AL) 7 August 2003 (2003-08-07) paragraph [0296]; figures 7,8,59	1-14, 18-21, 23,25
A	US 2002/169498 A1 (KIM CHEOL-SANG ET AL) 14 November 2002 (2002-11-14) the whole document	1-14, 18-21, 23,25

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
5 May 2006	23/05/2006

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Prechtel, A-K

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2006/000304

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 15-17,22,24
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2006/000304

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2004117004 A1	17-06-2004	NONE	
US 2003149475 A1	07-08-2003	US 2003040771 A1	27-02-2003
		US 2003040772 A1	27-02-2003
		US 7018401 B1	28-03-2006
US 2002169498 A1	14-11-2002	NONE	